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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,763	04/24/2001	Richard C. Willson III	009MUS	6416

26830 7590 08/28/2003
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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,763	WILLSON ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2003 has been entered.

Claim Rejections - 35 USC § 112

2. Claims 44, 48, 51, 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what is meant by the phrase "less than about 0.1 units" in claim 44. The phrase "less than" typically indicates a maximum point. The phrase "less than" however, is contraverted by the term "about" which implies that values above and below 0.1 units of endotoxin are permitted. Further, the extent of variance permitted by "about" is unclear in this context. In Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (CAFC 1991), the CAFC stated, "The district court held claims 4 and 6 of the patent invalid because their specific activity limitation of "at least about 160,000" was indefinite". After review, the CAFC states "We therefore affirm the district court's determination on this issue." Thus, the CAFC found the phrase

"at least about" indefinite where the metes and bounds of the term were not defined in the specification. Similarly, "less than about" is also indefinite.

Regarding claims 48, 51 and 54, the phrase "(i.e. hexamine ... chromium (III))" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 39-41, 43-46 and 56-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al (Biotechniques (1996) 21(1):92-99).

Davis teaches double CsCl banded DNA, specifically of vectors with luciferase or HBV envelope genes (see page 94, column 1).

Davis demonstrates that the DNA contains less than 3% RNA by weight (see figure 4, where the HPLC standard shows no RNA is present as well as page 97, column 1, where Davis states that no RNA was detected).

With regard to claims 40, 43, it is an inherent property of the double CsCl banded DNA that there is less than 0.0001 percent RNase by weight since the proteins are separated from the closed circular DNA in the centrifuge tube and the combination of alkaline lysis and two CsCl banding separations inherently achieve complete removal of

RNAse. Further, Davis notes that the preparation was free of protein contamination (see page 97, column 1).

With regard to claim 41, Davis teaches expression of HBV proteins for genetic immunization (see page 96, column 1).

With regard to claims 44-46, Davis expressly teaches that there is less than 0.012 EU/ug DNA (see page 97, column 2).

With regard to claims 56-58, Davis teaches purified double CsCl banded DNA which is inherently free of animal derived proteins and ribonucleases as discussed above. Further, Davis notes that the preparation was free of protein contamination (see page 97, column 1).

5. Claims 39-46 and 56-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Webster et al (Vaccine (1994) 12(8)1495-1498) as evidenced by Davis et al (Biotechniques (1996) 21(1):92-99).

Webster teaches double CsCl banded DNA, specifically of vectors with influenza proteins for use as a vaccine (see page 1495, column 2, subheading "DNA vaccines").

With regard to claims 40, 43-46 and 56-58, Davis evidences that CsCl double banded DNA is free of RNAse, protein contamination and endotoxin as discussed above. Therefore, the double CsCl banded DNA of Webster inherently meets the requirements of claims 40, 43-46 and 56-58.

6. Claims 39, 40 and 43-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Moradpour et al (Biochem. Biophys. Res. Comm. (1996) 221:82-88) as evidenced by Davis et al (Biotechniques (1996) 21(1):92-99).

Moradpour teaches a composition which comprises double CsCl banded DNA (see page 83, subheading "plasmid constructs") which is mixed with cholesteryl-spermidine (see page 83, subheading "transfection experiments").

With regard to claims 40, 43-46 and 56-58, Davis evidences that CsCl double banded DNA is free of RNase, protein contamination and endotoxin as discussed above. Therefore, the double CsCl banded DNA of Moradpour inherently meets the requirements of claims 40, 43-46 and 56-58.

With regard to claims 47-55, Moradpour expressly teaches a composition in which the double CsCl banded DNA is mixed with spermidine, which is a polyamine that is expressly listed in the claims (see page 83, subheading "transfection experiments").

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Butash et al (Biotechniques (2000) 29(3):610-619) also notes that CsCl banded DNA has less than 0.001 EU/ug DNA).

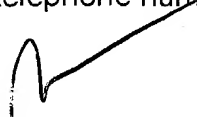
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman
Primary Examiner
Art Unit 1634